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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,755	03/24/2004	Paul D. Robbins	072396.0263	4352

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EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1633	

NOTIFICATION DATE	DELIVERY MODE
09/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/807,755	ROBBINS ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 30-32* is/are pending in the application.

4a) Of the above claim(s) *6-13 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,14,15,17-22 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 and 30-32 are pending in this application. Claims 23-29 have been cancelled.

Election/Restrictions

Applicant's election of Group I (Claims 1-22 and 30-32) in the reply filed on 2/9/07 and 7/11/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 23-29 have been cancelled.

Applicants' selection of SEQ ID NO:s 9, 16, 20 and 30 as well as human type 3 pol III promoter, JC virus gene and protein transduction domain is acknowledged. Accordingly, claims 6-13 and 16 are withdrawn from consideration for being drawn to non-elected subject matter but should the generic claims be found allowable, applicants will be entitled to consideration of claims to additional species, which depend from or otherwise require all limitations of an allowable generic claim.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically, figures 12 A, B and 19 contain sequences that are not identified by sequence identifier numbers. If the sequences can be found in the sequence listing it would be remedial to insert the appropriate SEQ ID NO:s. If not, a substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, CRF and letter stating that the contents of the sequence listing and the CRF are the same and contain no new matter is required. **The nature of the non-compliance did not preclude the examination on the merits of the instant application, the results of which follow.**

Drawings

Figure 7 is objected to under 37 CFR 1.83(a) because they fail to show any details as described in the specification. Specifically, figure 7 is a Western Blot. However, the details are indiscernible as the image is too dark. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 22 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The term "cells" defined by the specification at page states that the

cell is *in vitro* or *in vivo*. The scope of the claims, therefore encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "non-human" or "isolated" would be remedial. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30-32 are drawn to cancelled claims and as such lack antecedent basis.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)).

Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and In *re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claim is drawn to a DNA vector comprising a RNA promoter, a transcriptional terminator and a region to be transcribed wherein the vector is between 50-135 base pairs. The vector is designed to express ss or ds RNA molecules that may function as ribozymes or antisense siRNA. Applicants claim and disclose that the promoter can one of a series of RNA promoters whose disclosed sequences reveal that they are between 68 and 100 base pairs. As well, applicants disclose 12 vectors between 135 and 194 nucleotides. Hence, it is not clear how applicants intend on reducing the size below 135 nucleotides as they have not provided means to do so in the specification. The instant claim is drawn to a DNA vector comprising a RNA promoter, a transcriptional terminator and a region to be transcribed wherein the vector is between 50-135 base pairs. Applicants claim and disclose that the promoter can one of a series of RNA promoters whose disclosed sequences reveal that they are between 68 and 100 base pairs. As well, applicants disclose 12 vectors between 135 and 194 nucleotides. Hence, it is not clear how applicants intend on reducing the size below 135 nucleotides as they have not provided means to do so in the specification. Whether an invention is enabled or not does not break down to the question of whether individual components or steps of the invention have the potential of operating as intended but rather if the invention as a whole will function as recited. The instant disclosure does not provide adequate guidance for generation of vectors smaller then 135 base pairs. Though not controlling, the lack of working examples, is, nevertheless, a factor

to be considered in a case involving both physiological activity and an undeveloped art. When a patent applicant chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them. Ex parte Sudilovsky, 21 USPQ2d 1702, 1705 (BPAI 1991); In re Novak, 134 USPA 335 (CCPA 1962); In re Fouche, 169 USPQ 429 (CCPA 1971).

The invention has been assessed as it relates to the prior art, which does not teach that a vector can be generated, that is smaller then the single components that are required. As well, applicants do not provide the structural requirements of a vector less then 135 base pairs such that a person of skill in the art can identify those components that are not required of the disclosed vectors and that can still mediate expression of a region into an RNA molecule. Given the unpredictability of the art, the poorly developed state of the art with regard to predicting the structural/ functional characteristics of antagonists, the lack of adequate working examples and the lack of guidance provided by applicants, the skilled artisan would have to have conducted undue, unpredictable experimentation to practice the claimed invention.

The instant invention has been assessed completely as it relates to the prior art. However, whether an invention is enabled or not does not break down to the question of whether individual components or steps of the invention have the potential of operating as intended but rather if the invention as a whole will function as recited. The instant disclosure does not provide adequate guidance for Though not controlling, the lack of working examples, is, nevertheless, a factor to be considered in a case involving both physiological activity and an undeveloped art. When a patent applicant chooses to forego exemplification and bases utility on broad terminology and

general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them. Ex parte Sudilovsky, 21 USPQ2d 1702, 1705 (BPAI 1991); In re Novak, 134 USPA 335 (CCPA 1962); In re Fouche, 169 USPQ 429 (CCPA 1971). Given the unpredictability of the art, the poorly developed state of the art with regard to predicting the structural/ functional characteristics of antagonists, the lack of adequate working examples and the lack of guidance provided by applicants, the skilled artisan would have to have conducted undue, unpredictable experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 15 and 18, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brummelkamp et al (Science, 2002, Vol 296, pages 550-553) as evidenced by Oliogengine (pSuper RNAi System).

Brummelkamp et al teach a vector comprising synthetically overlapping oligonucleotides. The vector comprises a RNA promoter, a region to be transcribed into a RNA molecule and a termination signal (see e.g. .figure 1) as recited in claim 1. The vector is circular but as any circular vector can be linearized enzymatically or chemically (as evidenced by oligoengine, see

page 4) as recited in claims 2-3. The promoter is the H1-RNA promoter should be absent evidence to the contrary be the sequence set forth in SEQ ID NO:20 which is human H1 polymerase II as recited in claims 4 and 5. The vector further comprises a heteroduplex bubble, which is defined as a mismatch leading to a bubble, (see e.g. figure 2) as recited in claim 18 and encodes an antisense oligonucleotide (see e.g. figure 1) as recited in claim 15. The linear vector is between 50 and 2000 base pairs as recited in claim 21 as evidenced by oligoengine (see e.g. page 5 of oligoengine). The vector is transformed into cells as recited in claim 22 (see e.g. figure 3).

Claims 1-3 and 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Meissner et al (NAR, 2001, Vol 29, pages 1672-1682).

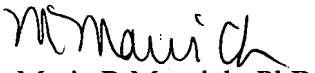
Meissner et al teach a vector comprising synthetically overlapping oligonucleotides. The vector comprises an inducible variant of an RNA promoter, a region to be transcribed into a RNA molecule and a termination signal (see e.g. .figure 2B and page 1674, col 2, paragraph 2) as recited in claim 1. The vector is circular as it is within pUC18 but as any circular vector can be linearized enzymatically or chemically (for example see oligoengine as set forth above) as recited in claims 2-3. The vector was histidine tagged and inserted into cells as recited in claim 19 and 22 (see e.g. page 1679, col 1, paragraph 3).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Maria B Marvich, PhD
Examiner
Art Unit 1633